Disposition: d

To: LOS-DO (FDA092)
To: ORA-DEEO (FDA206)
To: CFSAN-COMP (FDA209)
To: PRESS-WASH (FDA213)
To: PRESS-PKLN (FDA223)
From: FDA613 Delivered: Wed 25-Apr-90 20:33 EDT Sys 157 (179)
Subject: RECOMMENDATION &
Mail Id: IPM-157-900425-185090077

FOR FIRM INITIATED RECALL'

TO: HFF-314/CFSAN-COMP

INFO: HFC-162/ORA-DEEO
HFI-20/PRESS-PKLN
HFI-21/PRESS-WASH

FROM: HFR-PA295/LOS-DO R & E COORD.

SUBJECT: RECOMMENDATION FOR FIRM INITIATED RECALL

RECALLER CFN:	2027715
PAC:	03R800
PRODUCT CODE:	54YYL99
DATE OF EI:	3/26/90
SAMPLE COLLECTED:	90-446-414
RECALL START DATE:	3/30/90
FIRM'S ESTIMATED DATE OF COMPLETION:	6/90

RECOMMENDATION:

1. PRODUCT:

"MICRO-FLORA", A CONCENTRATED LIQUID FORM OF VIABLE ORGANISMS DESIGNED TO ASSIST IN THE REPLACEMENT AND MAINTENANCE OF FAVORABLE INTESTINAL BACTERIAL GROWTH. IT IS INTENDED TO BE TAKEN ORALLY, MIXED WITH WATER.

THE PRODUCT IS CONTAINED IN A WHITE OPAQUE RIGID PLASTIC BOTTLE WITH BLUE LETTERING. A LOGO OF A COLON ON THE FRONT LABEL PANEL IS PINK IN COLOR.

THE BOTTLE IS LABELED IN PART: "***MICRO-FLORA ***ONE PINT (16 OZ.)***INGREDIENTS: PURIFIED WATER, BACTERIA (BACILLUS LATEROS-PORUS), PROTEIN, NIACIN, VITAMIN B-12, TRACE MINERALS***AMINO ACIDS***0522***A PRODUCT OF MICRO-FLORA CORPORATION, 3537 OLD CONEJO ROAD, #115, NEWBURY PARK, CA 91320***".

TWELVE (12) BOTTLES ARE PACKAGED INTO A SHIPPING CASE. THE SHIPPING CASE IS LABELED IN PART "MICRO-FLORA CORP. 3537 OLD CONEJO RD., #115 NEWBURY PARK, CALIF. 91320***CODE NO. 0522***".

2. CODE:

ONE BATCH CODE OF THE PRODUCT IS BEING RECALLED, BATCH# "0522", WHICH IS LOCATED ON THE BOTTLE AND CASE LABELS.

3. RECALLING/RESPONSIBLE FIRM:

MICRO-FLORA CORPORATION
438A CALLE SAN PABLO
CAMARILLO, CA 93010

THE PRODUCT IS MANUFACTURED FOR MICRO-FLORA BY:

COSMETIC DEVELOPMENT SYSTEMS INC.
996 LAWRENCE DRIVE
NEWBURY PARK, CA 91320

4. REASON FOR RECALL RECOMMENDATION:

THE PRODUCT IS ADULTERATED, IN THAT IT CONTAINS A POISONOUS OR DELETERIOUS SUBSTANCE, KLEBSIELLA PNEUMONIAE, WHICH MAY RENDER IT INJURIOUS TO HEALTH.

THE HEALTH PROTECTION BRANCH OF HEALTH AND WELFARE, CANADA, REPORTED FINDING HIGH COUNTS OF KLEBSIELLA PNEUMONIAE IN THE

PRODUCT, RESULTING IN A RECALL OF THE PRODUCT IN CANADA BY THE CANADIAN DISTRIBUTORS.

PRELIMINARY RESULTS OF ANALYSIS OF THE PRODUCT BY SAN-DO (LOS-DO SAMPLE NO. 90-446-414) HAS ALSO REVEALED HIGH COUNTS OF THE PRESENCE OF KLEBSIELLA PNEUMONIAE IN THE PRODUCT.

THE FIRM REPORTED RECEIVING AT LEAST FIVE REPORTS THAT THE PRODUCT HAD A "FOUL" ODOR. NO INJURIES WERE REPORTED.

5. VOLUME OF PRODUCT IN COMMERCE:

A TOTAL OF 10,326 BOTTLES WERE MANUFACTURED. THE FIRM HELD 3,401 BOTTLES AT IT'S WAREHOUSE IN CAMARILLO, CA, AT THE ONSET OF THE RECALL. 6,925 BOTTLES WERE DISTRIBUTED THROUGH MARCH 1990. ON 3/30/90 THE FIRM ESTIMATED THAT LESS THAN 1,500 BOTTLES OF PRODUCT REMAINED IN COMMERCE.

6. DISTRIBUTION PATTERN:

DOMESTICALLY, THE FIRM SHIPPED THE PRODUCT TO APPROX. 120 CONSIGNEES (APPROX. 5% DISTRIBUTORS, 20% HEALTH FOOD STORES/ PHARMACIES, AND 75% PHYSICIANS/MEDICAL CLINICS), LOCATED IN 22 STATES (AK, AZ, CA, CO, FL, GA, HI, IL, LA, MD, ME, NC, NE, NJ, NM, NV, NY, OR, TX, UT, WA, WI). NO U.S. GOVERNMENT CONSIGNEES WERE REPORTED.

INTERNATIONALLY, THE FIRM SHIPPED THE PRODUCT TO TWO DISTRI-BUTORS IN CANADA:

7. FIRM'S RECALL STRATEGY:

MICRO-FLORA ISSUED TWO SEPARATE RECALL NOTICES VIA LETTER DATED 3/30/90. ONE LETTER WAS ADDRESSED TO DISTRIBUTORS AND THE OTHER LETTER WAS ADDRESSED TO THEIR USER CUSTOMERS. THE LETTERS IDENTI-FIED THE PRODUCT BEING RECALLED, IT'S USE, THE REASON FOR THE RECALL (CONTAMINATION), AND THAT THE CONTAMINATION COULD CAUSE STOMACH UPSET OR DIARRHEA. THE LETTER REQUESTED THAT CONSIGNEES QUARANTINE ALL PRODUCT AND HOLD IT FOR RETURN TO MICRO-FLORA. DISTRIBUTORS WERE REQUESTED TO SUBRECALL. A RESPONSE FORM WAS ATTACHED TO THE LETTER.

THE CONSIGNEES WERE INFORMED THAT, IF THEY HAVE ANY QUESTIONS CONCERNING THE RECALL, THEY MAY TELEPHONE MS. BRENDA SKALA, MICRO-FLORA CORP., AT (805) 389-6565.

MICRO-FLORA INTENDS TO FOLLOW-UP THE LETTER BY TELEPHONING ALL NONRESPONDING CONSIGNEES.

THE FIRM INTENDS TO USE THE RETURNED/HELD PRODUCT FOR RESEARCH PURPOSES.

TO PREVENT RECURRENCE OF THE PROBLEM, MICRO-FLORA INTENDS TO DISCONTINUE THE SERVICES OF THE MANUFACTURER, COSMETIC DEVELOPMENT SYSTEMS.

(MICRO-FLORA BELIEVES THE RECALL IS A CLASS III.) THEY ARE RECALLING TO THE USER LEVEL, AND DO NOT INTEND TO PUBLICIZE.

8. FIRM OFFICIAL:

CONTACT/RESPONSIBLE INDIVIDUAL:

BOYD J. O'DONNELL, PRESIDENT
MICRO-FLORA CORPORATION
438A CALLE SAN PABLO
CAMARILLO, CA 93010

TELEPHONE#: (805) 389-6565

9. DISTRICT AUDIT PROGRAM:

LOS-DO RECOMMENDS LEVEL A AUDIT CHECKS AT THE DISTRIBUTOR ACCOUNTS AND LEVEL C AUDIT CHECKS AT THE USER ACCOUNTS. IF THE RECALL APPEARS INEFFECTIVE AT THESE LEVELS, AFTER REQUESTING THAT THE FIRM REISSUE THE RECALL NOTICE TO IT'S CUSTOMERS, LOS-DO RECOMMENDS THE REAUDITS BE DONE AT THE SAME LEVEL. IF THIS RECALL IS CLASSIFIED AS A CLASS I, LOS-DO RECOMMENDS THAT A FDA PRESS RELEASE ISSUE, SINCE THE FIRM DOES NOT INTEND TO PUBLICIZE.

NOTE: SAN-DO HAS BEEN REQUESTED TO SEND THE FINAL RESULTS OF ANALYSIS (SUMMARY/WORKSHEETS) FOR SAMPLE# 90-446-414 TO HFF-314, WHEN COMPLETED. ALSO, SAN-DO IS ANALYZING ANOTHER SAMPLE, DIFFERENT CODE, OF THE PRODUCT (LOS-DO SAMPLE# 90-446-415). SAN-DO HAS REPORTED THAT PRELIMINARY RESULTS OF

ANALYSIS FOR THIS SAMPLE MAY BE NEGATIVE FOR K. PNEUMONIAE.

10. RECOMMENDING OFFICIALS:

RONALD L. KOLLER, CSO/CPK-RP
PAUL W. EVANS, ASCSO/CPK-RP
FRED B. PLETT, R&E COORD.

HEALTH HAZARD EVALUATION BOARD

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

The Problem: Dietary Supplement "Micro-Flora" Contaminated with Klebsiella Pneumoniae

HHE No.: 2402

Statement of Hazard

The Health Protection Board of Health and Welfare Canada found high levels of Klebsiella pneumoniae in this product. On March 22, 1990 the Health and Welfare Canada classified this as a Class I recall and issued a news release on march 23, 1990 warning consumers who have already used this product to contact a physician immediately if nausea, diarrhea, fever, chills, cough, abdominal or chest pain develop since Klebsiella pneumoniae may cause illnesses such as gastro-intestinal infections or pneumonia.

This product is manufactured by Cosmetic Development Systems, Inc., Newberry Park, CA for Micro-Flora Corporation, Camarillo, CA. The product is a concentrated liquid form of viable organisms designed to assist in the replacement and maintenance of favorable intestinal bacterial growth.

Analysis of the product (90-446-414) by SAN-DO revealed the presence of Klebsiella pneumoniae and oxytocia.

No complaints of illness or injury associated with this product have been reported by the District.

The Board agrees with the Canadian Health Protection Branch that this product may be used by the young and by individuals who are debilitated. Under these conditions of use, the product may pose an acute, life-threatening hazard to health.

Members Present

Donald A. Kautter for J. M. (HFF-23

Hamida Z. Khan, M.D. HFF-134

Jonathan Clarke MD HFF 230

Richard [illegible] MD HFF-268

5/24/90

Chairman or Authorized Representative

WPMAIL -DEC -ECHO
MAIL LOS-DO PRESS-WASH PRESS-PKLN ORA-DEEO LEG-AFFAIRS 'MICRO-FLORA'

FROM: DIRECTOR, DIVISION OF REGULATORY GUIDANCE, HFF-310

SUBJECT: RR 4/25/90, MICRO-FLORA CONCENTRATED LIQUID PACKAGED IN ONE PINT (16 OZ.) SIZE CONTAINERS CODED "0522"; THE PRODUCT IS LABELED IN PART "***MICRO-FLORA***ONE PINT (16 OZ.) ***INGREDIENTS: PURIFIED WATER. BACTERIA (BACILLUS LATEROSPORUS), PROTEIN, NIACIN, VITAMIN B-12. TRACE MINERALS***AMINO ACIDS***0522***A PRODUCT OF MICRO-FLORA CORPORATION. 3537 OLD CONEJO ROAD, #115, NEWBURY PARK, CA. 91320***"; MANUFACTURED BY COSMETIC DEVELOPMENT SYSTEMS INC., NEWBURY PARK, CA.; DISTRIBUTED AND RECALLED BY MICRO-FLORA CORPORATION, CAMARILLO, CA.

TO: LOS ANGELES DISTRICT, HFR-PA295
ATTN: FRED PLETT
R & E COORDINATOR

INFO: HFC-162, HFI-20, HFI-21

NUMBER F-522-0 HAS BEEN ASSIGNED TO THE SUBJECT RECALL .

THIS IS A CLASS I RECALL SINCE THIS SITUATION POSES A POTENTIAL ACUTE, LIFE THREATENING HAZARD TO HEALTH.

LEVEL A (100%) EFFECTIVENESS CHECKS MUST BE CONDUCTED BY THE FIRM TO ALL LEVELS OF DISTRIBUTION.

MODIFIED LEVEL C FDA AUDIT CHECKS ARE INDICATED WHICH INCLUDE ALL DIRECT ACCOUNTS AND 10% OF THE SUBACCOUNTS WITH THE UNDERSTANDING THAT IF THE 10% AUDIT FINDS THE RECALL EFFECTIVE, ADDITIONAL AUDITS WILL NOT BE REQUIRED.

THIS RECALL WILL BE LISTED IN THE WEEKLY FDA ENFORCEMENT REPORT. THE FIRM HAS RECEIVED A LETTER FORM HFC-1.

JANICE F. OLIVER

REASON: CONTAMINATED WITH KLEBSIELLA PNEUMONIAE

RECOMMENDATION FOR
RECALL TERMINATION

CLASS I RECALL
LEVEL A

TO: HFF-314
DATE: 7/3/91
CFN: 2027715
FIRM: MICRO-FLORA CORP.
438-A CALLE SAN PABLO
CAMARILLO, CA 93010

SECTION I - RECALL DATA

1. RECALL NUMBER:

F-522-0

2. PRODUCT INVOLVED:

MICRO-FLORA, CONCENTRATED LIQUID FORM OF VIABLE ORGANISMS; DESIGNED TO ASSIST IN THE REPLACEMENT AND MAINTENANCE OF INTESTINAL BACTERIAL GROWTH. LOT #0522.

3. QUANTITY MANUFACTURED:

A TOTAL OF 16,000-ONE PINT BTLS.

4. QUANTITY DISTRIBUTED AND DATES DISTRIBUTED:

A TOTAL OF 14,220 - ONE PINT BTLS. WERE DISTRIBUTED THROUGH MARCH 1990.

5. QUANTITY ON HAND AT ON-SET OF RECALL:

1,780-ONE PINT BTLS. WERE HELD AT THE ON-SET OF THIS RECALL AT THE FIRM'S WAREHOUSE.

6. DATE AND METHOD OF RECALL:

THE FIRM ISSUED TWO SEPARATE RECALL NOTIFICATION LTRS. ON 3/30/90; ONE ADDRESSED TO THE DISTRIBUTORS AND ONE TO THE USER LEVEL CUSTOMERS. BOTH LTRS. IDENTIFIED PRODUCT; ITS USE, REASON FOR RECALL AND ADVERSE AFFECTS ASSOCIATED WITH PRODUCT. ADDITIONALLY, LTRS. REQUESTED CONSIGNEES QUARANTINE ALL PRODUCT FOUND AND HELD FOR RETURN TO MICRO-FLORA. DISTRIBUTORS WERE ALSO REQUESTED TO SUBRECALL. A RESPONSE FORM ACCOMPANIED BOTH LTRS.

7. QUANTITY RECOVERED:

2,060 BOTTLES WERE RETURNED TO THE FIRM AS OF 9/17/90.

8. DISPOSITION OF RETURNS AND HELD STOCK:

ON 11-26-90, THE FIRM VOLUNTARILY DESTROYED 3,467 - ONE PINT BTLS. OF RECALLED PRODUCT. THESE INCLUDED STOCK IN FIRM'S WAREHOUSE AND RETURNED PRODUCT. THIS DESTRUCTION WAS WITNESSED BY THE STATE FDA AND CSO KOLLER OF CPK-RP.

9. SAMPLES COLLECTED:

90-446-414

10. DATE RECALL COMPLETED:

11-26-90

REMARKS (SECTION I):

AS OF LAST FALL SEPT. 1990, THE FIRM WAS DISSOLVED, AND IS NO LONGER IN BUSINESS ACCORDING TO W. PATRICK NOONAN, FORMER ATTORNEY OF THE FIRM.

SECTION II - VERIFICATION OF EFFECTIVENESS BY FIRM

APPLICABLE

UNABLE TO OBTAIN, SINCE FIRM IS OOB.

SECTION III - RESULTS OF FDA AUDIT PROGRAM

APPLICABLE

15. NUMBER OF AUDIT CHECKS BY TYPE OF CONSIGNEE:

40 - AUDIT CHECKS WERE CONDUCTED TO PHYSICIANS, PHARMACIES, HEALTH FOOD STORES, CLINICS AND DISTRIBUTORS.

16. HOW CONDUCTED (TELEPHONE OR VISIT):

16 - VISITS

24 - TELEPHONE(S)

17. RESULTS OF AUDIT CHECKS:

AUDIT CHECKS INDICATE RECALL WAS EFFECTIVE.

SECTION IV - ANALYSIS OF RECALL

19. NATURE OF THE VIOLATION/PROBLEM:

THE PRODUCT IS ADULTERATED, IN THAT IT CONTAINS A POISONOUS OR

DELETERIOUS SUBSTANCE: KLEBSIELLA PNEUMONIAE, WHICH MAY RENDER IT INJURIOUS TO HEALTH.

20. ACTION FIRM IS TAKING TO PREVENT SIMILAR PROBLEMS (DISTRICT EVALUATION):

THE FIRM HAS GONE OUT OF BUSINESS AS OF 9/90; ACCORDING TO THE FIRM'S ATTORNEY, MR. W. PATRICK NOONAN. NO OTHER INFORMATION REGARDING FIRM WAS AVAILABLE.

21. RELATIONSHIP OF THIS PROBLEM TO SIMILAR OR OTHER PRODUCTS AND TO OTHER FIRMS:

SEE F-708-0, FIRM RECALLED SAME PRODUCT FOR BACTERIA CONTAMINATION: AGROBACTRIUM RADIOBACTER.

22. DISTRICT REVIEW OF TOTAL RECALL EFFORT (STATUS REPORT REVIEW, EFFECTIVENESS CHECK REVIEW, ETC.):

FDA AUDIT CHECKS INDICATE THIS RECALL WAS EFFECTIVE. THE FIRM RECOVERED 2,060 BOTTLES. THIS AMOUNT IS A REASONABLE RECOVERY FOR A CONSUMABLE PRODUCT DISTRIBUTED AT LEAST 6 MONTHS PRIOR TO RECALL. THE RETURNS AND HELD STOCK WERE PROPERLY DESTROYED. NO ADDITIONAL COMPLAINTS WERE REPORTED. THE FIRM IS O/B. LOS-DO RECOMMENDS RECALL TERMINATION.

23. DISTRICT INSPECTION F/U:

NONE. FIRM IS O/B.

24. SUMMARY OF PRODUCT DEFECT COMPLAINTS OR ILLNESS/INJURIES:

THE FIRM HAS NOT RECEIVED ANY ADDITIONAL COMPLAINTS OF ILLNESS, INJURIES OR DEATHS ASSOCIATED W/PRODUCT.

25. LEGAL ACTIONS:

NONE. FIRM IS O/B.

RECOMMENDED BY/DATE:

Tina B. Santillanes for 7/5/91

TINA SANTILLANES
ASSIST. R & E COORDINATOR
LOS-DO

CONCURRENCE BY/DATE:

~~SHIRLEY ISBILL~~
DIRECTOR OF INVESTIGATIONS
LOS-DO 7-12-91

CENTER CONCURRENCE (CLASS I AND II)

Raymond E. Woodbury Deputy Director, DRG I HFF-310 JUL 30 1991

SIGNATURE, PRINTED NAME AND TITLE DATE

FDA

Enforcement Report

The FDA Enforcement Report is published weekly by the Food and Drug Administration, U.S. Public Health Service, Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities.

ENFORCE
07/03/1990

FDA ENFORCEMENT REPORT
FOR JULY 4, 1990

July 4, 1990

Recalls and Field Corrections:

FOODS

Class I - A situation in which there is a reasonable probability that the use of, or exposure to, a violative Product will cause serious adverse health consequences or death.

Product:	Micro-Flora, in 16 ounce bottles, a concentrated liquid form of viable organisms designed to assist in the replacement and maintenance of favorable intestinal bacterial growth. Recall #F-522-0.
Code:	Batch #0522.
Manufacturer:	Cosmetic Development Systems Inc., Newbury Park, California.
Recalled by:	Micro-Flora Corporation, Camarillo, California, by letter March 30, 1990. Firm-initiated recall ongoing.
Distribution:	Nationwide, Canada.
Quantity:	6,925 bottles were distributed.
Reason:	Product contains high Klebsiella pneumoniae counts.

Class II - A situation in which the use of, or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

NONE

Class III - A situation in which the use of, or exposure to a violative product is not likely to cause adverse health

consequences.

NONE

COSMETICS

NONE

HUMAN DRUGS AND BIOLOGICS

Class I -

NONE

Class II -

Product: Triamterene/Hydrochlorothiazide Tablets 75mg/50mg, in bottles of 100, 500 and 1,000 tablets, an Rx diuretic used for the treatment of hypertension under the following labels: American Therapeutics, Bioline Laboratories, Goldline Laboratories, Kaiser Foundation Hospitals, Major Pharmaceutical, Parmed Pharmaceuticals, Best Generics, Glenlawn, Harber Pharmaceutical, Martec Pharmaceutical, Moore Drug Exchange, Qualitest Product. Recall #D-296-0.

Code: Lot numbers:

805135	exp. 5/90	906176	exp. 6/91
806152	6/90	906177	6/91
806153	6/90	906186	6/91
807175	7/90	906187	6/91
807176	7/90	906189	6/91
807198	7/90	906190	6/91
807199	7/90	908241	8/91
808239	8/90	908242	8/91
808240	8/90	908243	8/91
808241	8/90	908244	8/91
808242	8/90	909278	9/91
810290	10/90	909279	9/91
810291	10/90	911363	11/91
812387	12/90	911364	11/91
901033	1/91	911365	11/91
901034	1/91	911367	11/91
902053	2/91	911368	11/91

-2-

902054	2/91	911369	11/91
902055	2/91	911370	11/91
904106	4/91	911375	11/91
904107	4/91	911376	11/91
904108	4/91	911377	11/91
904109	4/91.		

Manufacturer: American Therapeutics, Inc., Bohemia, New York.
Recalled by: Manufacturer, by telephone May 7, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide.
Quantity: Firm estimates 3-1/2 million tablets remain on market.
Reason: Lack of assurance of product meeting dissolution specifications.

Product: Humibid L.A. brand Guaifenesin Sustained-Release Tablets, in 100 tablet bottles, an Rx drug indicated for the temporary relief of coughs associated with respiratory tract infections and related conditions. Recall #D-303-0.

Code: Lot #0B1205 EXP 8/92.

Manufacturer: Adams Laboratories, Inc., Fort Worth, Texas.
Recalled by: Manufacturer, by letter May 15, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide.
Quantity: 3,980 bottles were distributed.
Reason: Some bottles may contain Deconsal II sustained-release tablets instead of Humibid L.A. sustained-release tablets. Each Humibid L.A. tablet contains 600 mg guaifenesin, whereas each Deconsal II tablet contains 60 mg pseudoephedrine and 600 mg guaifenesin.

Product: Kapectolin PG Antidarrheal, in 6 ounce and 16 ounce bottles, an OTC product under the following labels: Barre, Major, Goldline, Schein, Rugby, Bioline, Ascot, Qualitest, Baxter, United Research Labs, Moore. Recall #D-306-0.
Code: Lot #92261 EXP 9/93.
Manufacturer: Barre-National, Inc., Baltimore, Maryland.
Recalled by: Manufacturer, by letter May 9, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide.
Quantity: 111,325 bottles were distributed; firm estimates 2,250 bottles remain on market.
Reason: Product was distributed without adequate testing of the Belladonna Aklaloids component.

Product: Doxycycline Hyclate Capsules, 100 mg., an Rx broad spectrum antibiotic, in bottles of 50 and 500, under the Bioline, Goldline and Superpharm labels. Recall #D-312-0.
Code: All unexpired lots.
Manufacturer: Superpharm Corporation, Bayshore, New York.
Recalled by: Manufacturer, by letter June 18, 1990. Firm-initiated recall ongoing.
Distribution: Florida, California, Ohio, Texas, Connecticut, New York.
Quantity: 142,887 bottles of 50 and 19,883 bottles of 500 were distributed; firm estimates 12,700 bottles of 50 and 1,640 bottles of 500 remains on market.
Reason: Lack of assurance of bioequivalency and Abbreviated New Drug Application discrepancies.

Product: Organon brand Sterile Corticotrophin Zinc Hydroxide Suspension, USP, 40 units/ml, injection in 5 ml vials, an Rx drug used for diagnostic testing of adrenocortical function. Recall #D-313-0.
Code: Lot #189759 (vial), 2280189759 EXP 3/91 (carton).
Manufacturer: Organon, Inc., West Orange, New Jersey.
Recalled by: Manufacturer, by visit and by telephone beginning June 4, 1990 followed by letter June 6, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide.
Quantity: 8,946 vials were distributed.
Reason: Subpotency.

Product: (a) Red Blood Cells; (b) Platelets; (c) Fresh Frozen Plasma; (d) Single Donor Plasma; (e) Cryoprecipitated AHF; (f) Recovered Plasma. Recall #B-152/157-0.

Code: Unit numbers: (a) 56F47996, 56F50644, 56F65538, 56F67603, 56F70012, 56F71522, 56G56020, 56G62630, 56G66724, 56G67753, 56G72515, 56G72551, 56G82050, 56G85772, 56H24065, 56H32534, 56H43445, 56H46471, 56H47520, 56H47936, 56J24076, 56J36293, 56J37674, 56J44073, 56J47949, 56J50119, 56J56270, 56K33376, 56K37982, 56K40289, 56K45489, 56Q15466, 56Q16554, 56Q17359; (b) 56F65538, 56F71522, 56G66724, 56G85772, 56H32534, 56J36293, 56J37674, 56K37982, 56Q17359; (c) 56G72515, 56K45489; (d) 56H43445; (e) 56K45489; (f) 56F47996, 56F50644, 56F65538, 56F67603, 56F70012, 56F71522, 56G56020, 56G62630, 56G66724, 56G67753, 56G72551, 56G82050, 56G85772, 56H24065, 56H32534, 56H46471, 56H47520, 56H47936, 56J36293, 56J37674, 56J44073, 56J47949, 56J50119, 56J56270, 56K37982, 56K40289, 56Q15466, 56Q16554, 56Q17359.
Manufacturer: American Red Cross Blood Services, Albany, New York.
Recalled by: Manufacturer, by letter dated February 12 and 22, 1990. Firm-initiated recall ongoing.
Distribution: New York, Florida, California, Washington, D.C.

Quantity: (a) 34 units; (b) 9 units; (c) 2 units; (d) 1 unit; (e) 1 unit; (f) 29 units were distributed.
Reason: Blood components were distributed which tested either: 1) repeatably reactive for the antibody to the human immunodeficiency virus (anti-HIV-1) by EIA, or 2) nonreactive but were collected from donors who previously tested repeatably reactive for anti-HIV-1.

CORRECTION: Benadryl Elixir, Recall #D-286-0 which appeared in the June 6, 1990 Enforcement Report should read:

Product: Parke-Davis brand Benadryl Elixir, (Active ingredient 12.5 mg Diphenhydramine), in 5 ml unit dose bottles, 100 bottles/case, an Rx product used as an antihistaminic, for motion sickness, and antiparkinsonism.

Class III -

Product: Oxygen, USP, Medical Gas, an Rx product, in E and D size cylinders and home care liquid units of 92 pounds, under the American Care label. Recall #D-298-0.
Code: Not coded.
Manufacturer: American Care, Inc., Overland Park, Kansas.
Recalled by: Manufacturer, by visit May 14, 1990. Firm-initiated recall ongoing.
Distribution: Kansas.
Quantity: Firm estimates 18 D or E cylinders and 1 liquid home unit remain on market.
Reason: Current good manufacturing practice deficiencies.

Product: Oxygen, USP, Medical Gas, an Rx product, in D, E, H, HH and PG45 size cylinders, under Oxygen Service Co., and Midwest Gases labels. Recall #D-299-0.
Code: Lot numbers: 040402901, 050411902, 050416902, 050417902, 050417903, 050417904, 050418902, 050423902, 060426902, 060427902, 060427903, 060502902, 060504901, & 060507902.
Manufacturer: Oxygen Service Company, Springfield, Missouri.

Recalled by: Manufacturer, by visit May 17, 1990. Firm-initiated recall ongoing.
Distribution: Missouri.
Quantity: Approximately 495 cylinders were distributed; firm estimates 5 percent remains on market.
Reason: Current good manufacturing practice deficiencies.

-5-

Product: Red Blood Cells. Recall #B-150-0.
Code: Unit #5269093.
Manufacturer: Naval Hospital Blood Bank, Millington, Tennessee.
Recalled by: Manufacturer, by letter February 19, 1990. Firm-initiated recall complete.
Distribution: Tennessee.
Quantity: 1 unit was distributed and destroyed.
Reason: A unit of Red Blood Cells, collected from a donor who previously tested repeatably reactive for the antibody to the human immunodeficiency virus (Anti-HIV-1) was distributed.

MEDICAL DEVICES AND RADIOLOGY

Class I -

NONE

Class II -

Product: Schering Corporation InspirEase delivery system, mouthpieces and replacement mouthpieces:
(a) InspirEase Delivery System for Metered Dose Inhalers, an Rx device used in the facilitation of spray inhaler medications;
(b) InspirEase Mouthpieces, used as part of kit that is used for the facilitation of spray inhaler medications;
(c) InspirEase Replacement Mouthpieces, a component of an Rx device used as part of kit that is used for the facilitation of spray inhaler medications.
Recall #Z-676/678-0.
Code: Control numbers: (a) DDSS followed by 0110, 0731, 0802, 0807, 0808, 0814, 0815, 0821, 0822, 0824, 0825, 0915, 0925, 0927, 1002, 1009, 1020, 1108, 1114, 1117, 1120, 1121, 1204, 1206, 1211, 1214, 1229;
(b) IBMPS 0912, IBMPT 0109;
(c) IEVPS 0918, IEVPS 1012, IRMPS 0905, IRMPS 0907, IRMPS 1005, IRMPS 1127, IRMPS 1129, IRMPS 1220.
Manufacturer: Custom Plastic Development, Inc., Division of Custom Injection Molding, Kissimmee, Florida.
Recalled by: Schering Laboratories, Schering-Plough Corporation, Kenilworth, New Jersey, by letters beginning March 2, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide, Puerto Rico.
Quantity: 149,000 units were distributed.
Reason: Devices may not deliver the complete dosage of the medicated spray to the patient.

Product: Posterior Chamber Intraocular Lenses (IOL), a sterile Rx device: (a) Model P003UV; (b) Model 685UV; (c) Model 121UV. Recall #Z-679/681-0.
Code: Lot numbers: (a) V197; (b) V191; (c) U817.

Manufacturer: Storz Ophthalmics, Inc., Clearwater, Florida.
Recalled by: Manufacturer, by visit beginning January 15, 1990. Firm-initiated recall complete.
Distribution: Maryland, Florida, Washington state, Ohio, Illinois, Colorado, California, Tennessee, Michigan, Germany, Australia, France.
Quantity: 55 were implanted; none remains to be implanted.
Reason: There may be a discrepancy between the labeled refractive power and the actual correction provided by the lens.

Product: Naturalyte 4416-Acid Concentrate for Bicarbonate Dialysis, in 55 gallon drums and in 4/3.43 liter jugs, an Rx concentrated liquid used in conjunction with a basic concentrate in dialysis. Recall #Z-682-0.
Code: Lot numbers: E9E037, E9N168, E9E045, E9H033, E9J001.
Manufacturer: National Medical Care, Medical Products Division, Turlock, California.
Recalled by: National Medical Care, Rockleigh, New Jersey, by letter dated December 1, 1989. Firm-initiated recall ongoing.
Distribution: Arizona, California, Massachusetts, Missouri, Montana, New York, Oregon, Pennsylvania, Texas, Virginia, Washington state.
Quantity: 332 drums and 187 cases (4 jugs/case) were distributed.
Reason: The sodium chloride constituent of the product may precipitate out when the product is stored at the lower end of room temperature.

Product: Horizon 2000 Pulse Oximetry Monitor, Parts #260-OPT-865, #260-860-010, and #260-865-010 incorporating an Ohmeda pulse oximetry printed circuit board assembly (PCBA) and using Ohmeda light probes. The device determines a patient's arterial oxygen saturation and pulse rate by measuring the absorption of selected wavelengths of light. Recall #Z-683-0.
Code: All serial numbers.
Manufacturer: Mennen Medical Inc., Clarence, New York.
Recalled by: Manufacturer, by letter on or about March 14, 1990 followed by telephone and a second letter May 14, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide, India, Israel, Canada.
Quantity: 249 units were distributed.
Reason: The oximeter circuitry may not shut off the current by itself and may result in an overheated LED and probe.

Product: Model STR-270 Rotating Static Balancing Machine, utilizing a standard Spectra Physics Model 810 600 watt CO2 HeNe laser, used for balance correction in job shop applications. Recall #Z-684-0.
Code: Serial #2989.
Manufacturer: Balance Engineering Corporation, Troy, Michigan.
Recalled by: Manufacturer. FDA approved the firm's corrective

action plan September 12, 1989. Firm-initiated field correction complete.
Distribution: Ohio.
Quantity: 1 unit was distributed.
Reason: Noncompliance with the performance standard for laser products due to inadequate labeling, inadequate user information, lack of safety interlock, inadequate protective housing, lack of laser radiation emission indicator and inadequate beam attenuator.

Product: (a) Sigma 6000; (b) Sigma 6000+ Volumetric Infusion pump, a critical device for Rx use. Recall #Z-686/687-0.
Code: Numerous serial numbers are involved. Products affected are those with batteries bearing code numbers G10/88 through G16/89.
Manufacturer: Sonnenschein Batteries Inc., Cheshire, Connecticut (battery)
Recalled by: Smith & Nephew Sigma Inc., Medina, New York, by letter March 12, 1990. Firm-initiated field correction ongoing.
Distribution: Nationwide, Canada.
Quantity: Approximately 5,500 units were distributed.
Reason: These devices contain batteries with a defective vent diaphragm, which causes the battery to fail, resulting in the pump stopping.

Product: Kerr Unidose Composite Gun, a gun delivery system for unidose prefilled tips containing composite material for dental restorations. Recall #Z-693-0.
Code: Catalog #21782 -- All product on the market as of 5/3/90.
Manufacturer: Tenax Corporation, Danbury, Connecticut (contract injection molder).
Recalled by: Kerr Manufacturing Company, Romulus, Michigan, by letters of May 3 and 17, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide and international.
Quantity: 7,851 units were distributed.
Reason: The dental tip may fracture.

Product: Braasch Bulb Ureteral Catheters, catalog numbers: (a) 3326-06; (b) 3326-08; (c) 3326-10 (the last two numbers are the French sizes of the product). Recall #Z-694/696.

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Code: Lot numbers: (a) G990104, G990638;
(b) G086290, G086291, G086292, G086294 through G086298, G983308, G984215, G984409, G984410, G984901, G984902, G985003, G990408, G990818, G990819, G990820, G990821, G990822, G990825, G990826;
(c) G088438, G086515, G086516, G086763, G087214, G087215, G087216, G087346, G990105, G990114, G990115, G990117, G990412, G990501, G990827.
Manufacturer: TFX Medical/Rusch, Inc., Duluth, Georgia.
Recalled by: Manufacturer, by letter January 3, 1990. Firm-initiated recall ongoing.
Distribution: Nationwide, Canada.
Quantity: (a) 140 pieces; (b) 7,330 pieces; (c) 5,320 pieces were distributed.
Reason: The catheters may separate due to sterilization having caused the shaft to weaken in the area below the bulb.

The device tips may break off.

Class III -

NONE

VETERINARY PRODUCTS

NONE

Medical Device Safety Alerts:

Product:	Barium Enema Kits and all components, used for diagnosis of lower G.I. ailments, sold in complete kits ready to use, kits without barium sulfate in individual pieces, and bulk barium sulfate. Safety Alert #M-055-0.
Code:	All lots.
Manufacturer:	E-Z-EM Inc., Westbury, New York.
Alerted by:	Manufacturer, by letter and by telegram May 17, 1990.
Distribution:	Nationwide and international.
Quantity:	Unknown.
Reason:	Potential adverse (allergic vasovagal or anaphylactoid) reactions associated with the use of the product.